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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte EREZ GOLAN

Appeal 2014-009091
Application 13/055,507
Technology Center 3700

Before LINDA E. HORNER, THOMAS F. SMEGAL, and LISA M. GUIJT, *Administrative Patent Judges*.

GUIJT, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant[1] seeks our review under 35 U.S.C. § 134 of the Examiner's decision[2] rejecting claims 1–14 and 16–22. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

CLAIMED SUBJECT MATTER

Claims 1 and 22 are independent. Claim 1 is reproduced below.

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[1] Appellant identifies the real party in interest as Pi-R-Squared Ltd. Br. 1.
[2] Appeal is taken from the Final Office Action dated February 6, 2013 ("Final Act.").

1. A device for fracturing calcifications in heart valves comprising:

an impactor catheter configured for percutaneous delivery to a heart valve;

an impact-producing element disposed at a distal portion of said catheter and operative to vibrate and create a mechanical impact when deployed out of an external housing of said catheter and brought into contact with a calcification at a leaflet of said heart valve;

an energy source operative to vibrate said vibrating impact-producing element so that said impact-producing element fractures the calcification without necessarily removing the calcification from the leaflet; and

an anvil against which the calcification is struck by said impact-producing element.

REJECTIONS

I. Claims 1, 3, 4, and 22 stand rejected under 35 U.S.C. § 102(b) as anticipated by Kassab (US 2010/0198211 A1; pub. Aug. 5, 2010).

II. Claims 1, 4, 5, 13, 21, and 22 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Pedersen (US 2005/0075662 A1; pub. Apr. 7, 2005).

III. Claim 2 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Pedersen and Brisken (US 5,846,218; iss. Dec. 8, 1998).

IV. Claims 6 and 20 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Pedersen and Zadno-Azizi (US 6,022,336; iss. Feb. 8, 2000).

V. Claim 8 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Pedersen and Evans (US 5,916,229; iss. June 29, 1999).

VI. Claim 9 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Pedersen and Salahieh '696 (US 2005/0137696 A1; pub. June 23, 2005).

VII. Claim 14 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Pedersen and Salahieh '872 (US 2006/0058872 A1; pub. Mar. 16, 2006).

VIII. Claims 16 and 18 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Pedersen, Salahieh '696, and Galdonik (US 2005/0085847 A1; pub. Apr. 21, 2005).

IX. Claims 17 and 19 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Pedersen, Salahaieh '696, and Leone (US 2006/0253148 A1; pub. Nov. 9, 2006).

X. Claims 1, 2, and 21 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Zadno-Azizi and Brisken.

XI. Claim 11 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Zadno-Azizi, Brisken, Saadat (US 5,827,269; iss. Oct. 27, 1998) and Hong (US 2002/0125842 A1; pub. Sept. 12, 2002).

XII. Claims 1, 4, and 7 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Noriega (US 2005/0228418 A1; pub. Oct. 13, 2005) and Shturman (US 5,295,958; iss. Mar. 22, 1994).

XIII. Claims 1 and 10 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Gifford (US 2006/0229659 A1; pub. Oct. 12, 2006) and Shturman.

XIV. Claims 1, 4, 21, and 22 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Lemelson (US 5,728,123; iss. Mar. 17, 1998) and Lary (US 5,649,941; iss. July 22, 1997).

ANALYSIS

Rejection I

Independent claim 1 and dependent claim 3 and 4

Regarding independent claim 1, the Examiner finds, *inter alia*, that Kassab's first and second umbrellas 102, 104 correspond to the claimed impact-producing element, and Kassab's drill 114 corresponds to the claimed anvil. Final Act. 2. The Examiner determines that Kassab discloses that "the calcification is struck by the impact-producing element" (umbrella 102 or 104) against the anvil (drill 114). *Id.* (citing Kassab ¶¶ 48–50). The Examiner further determines that "[i]f the prior art structure is capable of performing the intended use, then it meets the claim," and that here, Kassab discloses "an impact-producing element . . . capable of being opened and closed repeatedly against the anvil having the form of a drill and generating vibration." Ans. 16. Appellant argues that Kassab's drill 114 is not an anvil and is not capable of being used as an anvil. Br. 25 (citing Kassab ¶ 51).

The Examiner has not directed us to, nor can we find, support in Kassab that drill 114 is an anvil against which something, such as a calcified aortic valve, is being struck.[3] Rather, Kassab consistently discloses that

[3] Appellant submits that the claim term "anvil" means "a structure against which something is hit by an impactor." Br. 31.

"[d]rill **114** may comprise one or more blades operable to grind, for example, a calcified aortic valve," [and] "allow for the pulverization of the calcific calcium material at the level of the aortic leaflet." *Id.* ¶ 51; *see also, e.g.*, ¶ 59 ("drill **612** may be operated to grind (or chop) cauterized calcified aortic valve **608** into small pieces"). Kassab discloses

> [rotatably coupling the] mechanical drill . . . to the shaft [of a] catheter . . . between the first umbrella and the second umbrella, positioning the umbrella device within an aperture within the valve, deploying the first umbrella on a first side of the valve, wherein the deployed first umbrella engages the valve at the first side of the valve, deploying the second umbrella on the second side of the valve, wherein the deployed second umbrella engages the valve at the second side of the valve, *operating the mechanical drill to grind the valve*, collapsing the first umbrella and the second umbrella to facilitate withdrawal of the umbrella device from the vessel, and withdrawing the umbrella device from the vessel.

Id. ¶ 13 (emphasis added). Alternatively, the umbrellas may include cauterizing wires on their circumferential edges "to excise the valve from the vessel prior to the step of operating the mechanical drill to grind the valve." *Id.*

Moreover, the Examiner fails to provide a reason tethered to, or grounded in, some rationale to believe that the blades of Kassab's drill are capable of functioning as an anvil against which the calcified aortic valve is struck by repeatedly opening and closing the umbrellas when the umbrellas are deployed and brought into contact with a calcification at a leaflet of the heart valve, as required by claim 1. "[W]here the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing

novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on." *In re Swinehart,* 439 F.2d 210, 213 (CCPA 1971). Nevertheless, the examiner must establish a sound basis for the examiner's belief that the functional limitation is an inherent characteristic of the prior art before the burden shifts to the applicant. *See In re Spada,* 911 F.2d 705, 708 (Fed. Cir. 1990).

Accordingly, we do not sustain the Examiner's rejection of independent claim 1, and claims 3 and 4 depending therefrom under 35 U.S.C. § 102(b) as anticipated by Kassab.

Independent claim 22

Regarding independent claim 22, Appellant argues that, with respect to Kassab's umbrellas, "there is only one single opening or one single closing – not cyclical movement, so there is no teaching of vibration." Br. 26.

Kassab describes deploying and collapsing the umbrellas for facilitating insertion and removal of the device, and for engaging and cauterizing the valve, as discussed *supra*. *See, e.g.*, Kassab ¶ 13. Kassab also discloses that "first umbrella **604** and second umbrella **606** may comprise magnetic material so that [the umbrellas] may be magnetically attracted to shaft **614** . . . [and] may collapse inwards to shaft **614**, exerting an inward force to further crush the calcified debris and close [the umbrellas]." Kassab ¶ 61. However, as stated *supra*, we agree with

Appellant that the Examiner fails to provide an adequate reason to believe that Kassab's umbrellas are capable of being vibrated so as to fracture calcifications "when [the umbrellas are] deployed . . . and brought into contact with a calcification at a leaflet of said heart valve," as required by claim 22.

Accordingly, we do not sustain the Examiner's rejection of claim 22 under 35 U.S.C. § 102(b) as anticipated by Kassab.

Rejection II

Regarding independent claims 1 and 22, the Examiner finds, *inter alia*, that Pedersen's catheter balloon 376 corresponds to the claimed anvil, and that Pedersen's expandable anchoring petals 374 correspond to the claimed impact-producing element. Final Act. 3 (*see, e.g.*, Pedersen ¶ 134 ("Petal Anchoring Catheter"; Figs. 14A, 14B). The Examiner also finds that Pedersen discloses that the Petal Anchoring Catheter embodiment may be used as a fixed platform. Ans. 16. The Examiner further finds that Pedersen's "Mesh Anchoring Ring" embodiment discloses a high energy low frequency ultrasound energy source, "which is well known to be capable of vibrating such that the impact-producing element fractures the calcifications without necessarily removing the calcification from the leaflet." Final Act. 4 (citing Pedersen ¶ 147; Fig. 23; *see also* ¶ 143). The Examiner reasons that it would have been obvious "to have provided the balloon catheter [(depicted in Figure 14B of Pedersen)] with an energy source, as taught by Pedersen, to deliver and position high energy sources to debulk valve leaflets." *Id.* The Examiner concludes that using Pedersen's

Petal Anchoring Catheter as a fixed platform to deliver and position ultrasound for debulking valve leaflets would result in "oscillating movement of the catheter" and therefore, the "balloon and petals would provide vibration." Ans. 16.

Appellant argues that Pedersen does not teach "an energy source operative to vibrate said vibrating impact-producing element so that said impact-producing element fractures the calcification," as required by claims 1 and 22. Br. 27. In support, Appellant submits that, with respect to the ultrasound energy, "Pedersen teaches [using] the catheter to deliver an energy source," including an ultrasound energy source, but to rely on such a disclosure for teaching the use of the energy source to vibrate Pedersen's expandable anchoring petals 374 to fracture calcifications is to engage in impermissible hindsight. *Id.*

Figures 14A and 14B depict an embodiment titled, "Petal Anchoring Catheter," wherein expandable anchoring petals 374 expand against aortic root walls to "stabilize and prevent movement of the petal anchoring catheter **370** before and during balloon inflation." Pedersen ¶¶ 134, 135. Pedersen explains that

> [i]n operation, the petal anchoring catheter **370** is positioned so that the catheter balloon **376** passes through the aortic valve. Next, the anchoring petals **374** are deployed, engaging the aortic root wall **123** and the inferior recesses of the aortic sinuses near the annulus **125**, preventing the petal anchoring catheter **370** from longitudinal movement. Finally, the catheter balloon **376** is inflated so as to push open the valve leaflets **126**. The catheter balloon **376** is then deflated but may be inflated multiple times to achieve a desired leaflet flexibility and pressure gradient

> reduction. When this has been achieved, the anchoring petals **374** are retracted and the petal anchoring catheter **370** is removed from the patient.

Id. ¶ 139. Pedersen does not disclose vibrating anchoring petals 374, which anchor the catheter, or an energy source operative to vibrate anchoring petals 374. Pedersen discloses that "the petal anchoring catheter **360** and **370** may be used as a fixed platform on which prosthetic implants can be delivered to and deployed on the aortic valve." Pedersen ¶ 142.

Figures 23 A–C of Pedersen depict an embodiment titled, "Mesh Anchoring Ring," wherein a balloon catheter 550 has an expandable mesh anchoring disk 556, which anchors the balloon catheter when expanded, such that catheter balloon 552 may be inflated to open valve leaflets 126. Pedersen ¶¶ 143, 146. Pedersen further discloses that "balloon catheter **550** may be further used as a fixed platform on which prosthetic implants can be delivered to and deployed on or adjacent to the aortic valve," and that "[i]n addition, this fixed platform can be used to deliver and position high energy sources for debulking valve leaflets such as excimer lasers, high energy low frequency ultrasound and radio frequency." *Id.* ¶ 147.

Thus, because Pedersen discloses using the Petal Anchoring Catheter as a fixed platform for delivering and deploying prosthetics and also using the Mesh Anchoring Ring as a fixed platform to deliver and position energy sources such as ultrasound sources, we determine that it would have been obvious to use the Petal Anchoring Catheter as a fixed platform for delivering and deploying energy sources such as ultrasound sources. However, we agree with Appellant that these disclosures in Pedersen do not

suggest using ultrasound sources to vibrate anchoring petals 374 of Pedersen's Petal Anchoring Catheter, which are for the express purpose of anchoring the balloon catheter, or that by delivering and deploying energy sources using Pedersen's Petal Anchoring Catheter, anchoring petals 374 would be caused to vibrate by the ultrasound energy source so that anchoring petals 374 fracture the calcification against catheter balloon 376. Nor does the Examiner provide an adequate reason to believe that the claimed subject matter would result from the Examiner's proposed modification. Therefore, absent hindsight, we see no reason why a person of ordinary skill in the art would have been led to modify Pedersen's Petal Anchoring Catheter to include an energy source operative to vibrate anchoring petals 374.

Accordingly, we do not sustain the Examiner's rejection of independent claims 1 and 22, and claims 4, 5, 13, 21, and 22 depending therefrom under 35 U.S.C. § 103(a) as unpatentable over Pedersen.

Rejections III–IX

Claims 2, 6, 8, 9, 14, and 16–20 depend from independent claim 1. The Examiner's reliance on Brisken, Zadno-Azizi, Evans, Salahieh '696, Salahieh '872, Galdonik, and/or Leone does not cure the deficiency in the Examiner's finding with respect to Pedersen as applied to claim 1 as discussed *supra*. Final Act. 4–9. Accordingly, for the same reasons stated *supra* with respect to Pedersen as applied to claim 1, we do not sustain the Examiner's rejection of claims 2, 6, 8, 9, 14, and 16–20 under 35 U.S.C.

§ 103(a) as unpatentable over Pedersen, and Brisken, Zadno-Azizi, Evans, Salahieh '696, Salahieh '872, Galdonik, and/or Leone.

Rejection X

Regarding independent claim 1, the Examiner finds, *inter alia*, with reference to Figure 18D, that Zadno-Azizi's balloon 426 corresponds to the claimed impact-producing element, and that Zadno-Azizi's balloon 402 corresponds to the claimed anvil. Final Act. 9. The Examiner determines that "the calcification is struck [against the anvil (balloon 402)] by the impact-producing element [(balloon 426)]." *Id.* Alternatively, the Examiner determines that "if a calcification was located between the anvil ([balloon] 402) and the impact-producing element ([balloon] 426), the calcification would be capable of being hit against anvil by the impact producing element." Ans. 17. Appellant argues that "[e]lement 402 is merely another balloon which is distal to balloon 426 and is no way the structure of an anvil for 426." Br. 31.

Zadno-Azizi discloses that main catheter 410 has balloon 412 ("an occlusive device") and guidewire 400 has balloon 402 ("an occlusive device"), such that balloons 402, 412 are inflated to create an isolated chamber or working space within vessel 414 that surrounds occlusion 406, wherein therapeutic procedures can be undertaken to remove or reduce occlusion 406 without risk of unwanted particles or emboli escaping into the blood stream. *See* Zadno-Azizi 19:66 to 20:31; Fig. 18A. Zadno-Azizi further discloses that once the chamber has been created around the occlusion, intermediate catheter 420 ("therapy catheter") is delivered to the

site of occlusion 406, including a "catheter carrying . . . [a] balloon for use in balloon angioplasty" or catheter-delivered ultrasound device to ablate plaque within the vessel. *See id.* at 20:61–67, 21:3–4, 12–14; Fig. 18B. Specifically, Zadno-Azizi discloses that "balloon angioplasty catheter **420** is positioned such that the distal end with the balloon **426** thereon is at the site of the occlusion **406**," and that "balloon **426** is inflated with a suitable inflation medium . . . to cause compression of the plaque of the occlusion **406** against the sidewall of the lumen **414**." *Id.* at 21:26–36, Fig. 18D. Thus, Zadno-Azizi does not disclose that occlusion 406 is struck against balloon 402. Moreover, Zadno-Azizi describes balloon 402 as a device that occludes vessel 414 to form one end of a chamber, not an anvil against which anything (including occlusion 406) is struck. Zadno-Azizi also does not disclose that a calcification is ever situated between balloon 402 and balloon 426, such that balloon 402 would function as an anvil, as speculated by the Examiner.

Accordingly, we do not sustain the Examiner's rejection of independent claim 1 and claims 2 and 21 depending therefrom under 35 U.S.C. § 103(a) as unpatentable over Zadno-Azizi and Brisken.

Rejection XI

Claim 11 depends from independent claim 1. The Examiner's reliance on Saadat and Hong does not cure the deficiency in the Examiner's finding with respect to Zadno-Azizi as applied to claim 1 as discussed *supra*. Final Act. 10–11. Accordingly, for the same reasons stated *supra* with respect to Zadno-Azizi as applied to claim 1, we do not sustain the

Examiner's rejection of claim 11 under 35 U.S.C. § 103(a) as unpatentable over Zadno-Azizi, Brisken, Saadat, and Hong.

Rejection XII

The Examiner finds, *inter alia*, that distal tip 24 of Noriega's drive shaft 22 is an impact-producing element capable of vibrating, however, that Noriega "fails to disclose an anvil against which the calcification is struck by the impact-producing element." Final Act. 11–12 (citing Noriega ¶ 53). The Examiner relies on Shturman for disclosing anchoring balloon 24, which "is expanded to position and stabilize the device." *Id.* at 12. The Examiner reasons that it would have been obvious "to have provided a balloon catheter having an anchoring balloon mounted thereon to the device of Noriega, as taught by Shturman, to provide means to stabilize the device when positioned within the treatment area." *Id.* Appellant argues that "Shturman has nothing to do with an anvil; an anchor is not an anvil." Br. 31.

The Examiner responds by noting that Appellant's Specification discloses that a balloon "may be used an anvil." Ans. 17 (citing Spec. ¶ 62; Fig. 8i (reference numeral 30). The Examiner further determines that "Noriega discloses an impactor catheter that may be stabilized with balloons to provide more control when removing occlusive material," and that "Shturman teaches a device that is used to remove occlusion and that utilizes an anchoring balloon to position and stabilize the device," concluding that "if calcification is located between the impact-producing element and the balloon of Shturman when the balloon is expanded to stabilize the device of

Noriega, the impact-producing elements are capable of hitting the calcification against the balloon as the energy source vibrates the shaft that is connected thereto." *Id.*

Shturman discloses that "distal portion **25** of the anchoring balloon [catheter **24**] is preferably of a larger diameter, having a shoulder **26** that contacts the inferior surface of the valve leaflets **12** to accurately and securely position the anchoring balloon **24**, with respect to the valve leaflets **12**, *providing support to the leaflets to stabilize their positions*." Shturman 4:50–56, Fig. 1 (emphasis added); *see also id.* at 10:36–43, Figs. 24–26A; 10:65–11:12, Fig. 25.[4] Thus, a preponderance of evidence supports the Examiner's finding that Shturman discloses that anchoring balloon 24, and especially its distal portion 25, provides a supporting surface for the valve leaflets. In addition, Appellant's argument does not apprise us of error in the Examiner's determination or reasoning that such distal portion 25 would function as an anvil against which occlusive material would be struck by Noriega's distal tip 24 of Noriega's drive shaft 22, according to the Examiner's proposed modification.

Accordingly, we sustain the Examiner's rejection of independent claim 1 under 35 U.S.C. § 103(a) as unpatentable over Noriega and Shturman. Appellant chose not to present separate arguments for the

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[4] Notably, Shturman also discloses that the deposit removal tool may be "an ultrasonic vibration generator **144** (e.g., of the type that generates vibrations in the range of 20,000 Hz) . . . connected to a wire **145** having a distal tip positionable adjacent the calcified deposits, the wire **145** being capable [of] conveying ultrasonic vibrations." *Id.* at 12:29–33, Fig. 34.

patentability of claims 4 and 7, which depend from claim 1, and therefore, we also sustain the Examiner's rejection of claims 4 and 7 under 35 U.S.C. § 103(a) as unpatentable over Noriega and Shturman. Br. 31.

Rejection XIII

The Examiner finds, *inter alia*, that ball 252 of Gifford "is capable of vibrating to create a mechanical impact," however, that Gifford "fails to disclose an anvil against which the calcification is struck by the impact-producing element." Final Act. 12–13 (citing Gifford ¶ 103). The Examiner relies on Shturman for disclosing anchoring balloon 24, which "is expanded to position and stabilize the device." *Id.* at 13. The Examiner reasons that it would have been obvious "to have provided a balloon catheter having an anchoring balloon mounted thereon to the device of Gifford, as taught by Shturman, to provide means to stabilize the device when positioned within the treatment area." *Id.* Appellant argues that "Shturman has nothing to do with an anvil; an anchor is not an anvil." Br. 32.

As discussed *supra* with respect to Rejection XII, Shturman discloses that anchoring balloon 24, and especially its distal portion 25, provides a supporting surface for the valve leaflets, and Appellant's argument does not apprise us of error in the Examiner's determination or reasoning that such distal portion 25 would function as an anvil against which the calcific deposits in and around the aortic valve would be struck by Gifford's ball 252, according to the Examiner's proposed modification.

Accordingly, we sustain the Examiner's rejection of independent claim 1 under 35 U.S.C. § 103(a) as unpatentable over Gifford and

Shturman. Appellant chose not to present separate arguments for the patentability of claim 10, which depends from claim 1, and therefore, we also sustain the Examiner's rejection of claim 10 under 35 U.S.C. § 103(a) as unpatentable over Gifford and Shturman. Br. 31–32.

Rejection XIV

Regarding independent claims 1 and 22, the Examiner finds, *inter alia*, that Lemelson's catheter device 9 is an impactor catheter, including blade support arms 16, "capable of being brought into contact with a calcification at a leaflet of the heart valve" and that Lemelson's balloon 11 is an anvil "in the form of a balloon against which the calcification is struck by the impact-producing element." Final Act. 13–14 (citing Lemelson ¶¶ 48–50). Appellant argues that "balloon 11 is not an anvil; nothing is ever hit or impacted against balloon 11 and balloon 11 is not arranged to act as an anvil." Br. 32. In support, Appellant submits that "[e]lements 16 . . . can only impact outwards" and as such "elements 16 . . . are not capable of impacting tissue against balloon 11; no force element is provided for such inward impact." *Id.* The Examiner responds that "if calcification is located between the impact-producing element and the anvil, the repelling and attracting of the impact-producing element is capable of hitting against [the] balloon such that the balloon may act as an anvil." Ans. 18.

Lemelson discloses that "catheter device **9** includes an elongated flexible tubular structure **10** having an expandable balloon **11** secured around its distal end" and that "[e]ither secured to or integral with the tubular structure **10** is an annular collar **15** to which are mounted one or

more cutting blades **18** by means of blade support arms **16**." Lemelson 3:39–41, 50–53. Lemelson further discloses that "[w]ith the balloon **11** deflated, the catheter is able to be positioned at the operative site without being encumbered by the extended cutting blades," and that "[o]nce the distal end is correctly positioned, the cutting blades may be extended simply by inflation of the balloon **11**." *Id.* at 4:7–12; *see also id.* at 4:1–4 ("FIG. **1**B shows the catheter with blades **18** in an extended and operable position whereby expansion of balloon **11** has forced the blade support arms **16** radially outward to thereby operatively extend the cutting blades **18**."). Lemelson explains that "to cut plaque from the artery walls, the blades **18** are rotated," or "vibrational energy may be transmitted to the blades **18**." *Id.* at 4:12–15. Thus, in Lemelson, balloon 11 is disclosed as a mechanism for deploying the cutting blades, however, a preponderance of evidence fails to support the Examiner's finding that balloon 11 is used as an anvil. Lemelson also fails to support the Examiner's determination that Lemelson discloses locating plaque from the artery walls between balloon 11 and blades 18.

Accordingly, we do not sustain the Examiner's rejection of independent claims 1 and 22, and claims 4 and 21 depending therefrom, under 35 U.S.C. § 103(a) as unpatentable over Lemelson and Lary.

DECISION

The Examiner's decision to reject claims 1, 3, 4, and 22 under 35 U.S.C. § 102(b) as anticipated by Kassab is REVERSED.

The Examiner's decision to reject claims 1, 4, 5, 13, 21, and 22 under 35 U.S.C. § 103(a) as unpatentable over Pedersen is REVERSED.

The Examiner's decisions to reject claims 2, 6, 8, 9, 14, and 16–20 under 35 U.S.C. § 103(a) as unpatentable over Pedersen, Brisken, Zadno-Azizi, Evans, Salahieh '696, Salahieh '872, Galdonik, and/or Leone are REVERSED.

The Examiner's decision to reject claims 1, 2, and 21 under 35 U.S.C. § 103(a) as unpatentable over Zadno-Azizi and Brisken is REVERSED.

The Examiner's decision to reject claim 11 under 35 U.S.C. § 103(a) as unpatentable over Zadno-Azizi, Brisken, Saadat, and Hong is REVERSED.

The Examiner's decision to reject claims 1, 4, and 7 under 35 U.S.C. § 103(a) as unpatentable over Noriega and Shturman is AFFIRMED.

The Examiner's decision to reject claims 1 and 10 under 35 U.S.C. § 103(a) as unpatentable over Gifford and Shturman is AFFIRMED.

The Examiner's decision to reject claims 1, 4, 21, and 22 under 35 U.S.C. § 103(a) as unpatentable over Lemelson and Lary is REVERSED.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART